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TITLE: Auricular Therapy for Treatment of Musculoskeletal Pain in the Setting of Military Personnel: A Randomized Trial

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## Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	4
Reportable Outcomes.....	4
Conclusion.....	4
References.....	4
Appendices.....	5-6

## **INTRODUCTION:**

Musculoskeletal injuries resulting in pain are one of the most common reasons for disability and missed duty among military personnel. Preliminary research has shown auricular therapy as a potential adjunctive treatment in this setting. This study will be a randomized trial of 250 subjects examining whether the addition of a specific auricular therapy protocol to standard care will have a beneficial impact on the pain and functionality of subjects who sustain an acute or sub-acute musculoskeletal injury. Specifically, the research study will attempt to determine whether auricular therapy provides a) more rapid and significant pain relief than usual care; b) more rapid and significant relief of co-morbidities related to pain (sleep disruption, mood changes, etc) than usual care; c) more rapid and significant return of functional ability than usual care; and d) more rapid and significant reduction in need for other therapies including pain medication?

## **BODY:**

The research project has not yet initiated due to difficulty in finalizing a clinical site in theater with investigators trained in the protocol (auricular therapy). After moving the project to the Naval Medical Center San Diego, the site PI has been deployed and we have recently confirmed Dr. Diana Fu MD as the Navy PI. At this point the protocol has been submitted to the Navy IRB and was reviewed in November, 2012. We are currently completing the necessary revisions in anticipated approval by early 2013. Other key steps completed thus far have included obtaining letter of support from the command at the Naval Medical Center and securing a medical safety officer with experience in the area (Dr. Branch). We have also confirmed statistical and data support through Dr. Paul Mills at UCSD. At this point we are hoping to confirm local IRB approval and to proceed with TATRC final review before initiation of the study.

## **KEY RESEARCH ACCOMPLISHMENTS:**

- Site approval at Naval Medical Center San Diego
- Letter of support obtained from the Naval Command
- Submission and initial review of protocol by Navy IRB
- Identification of key personnel: Navy investigators, safety officer and statistician
- Study questionnaires completed (timeline as attached in Appendix)

## **REPORTABLE OUTCOMES:**

- No reportable outcomes have resulted from this research as of this time.

## **CONCLUSION:**

We are anticipating local IRB approval and proceeding to final TATRC approval and study initiation in 2013.

## **REFERENCES:**

Hauret KG, Jones BH, Bullock SH, Canham-Chervak M, Canada S. Musculoskeletal injuries description of an under-recognized injury problem among military personnel. Am J Prev Med. 2010 Jan;38(1 Suppl):S61-70.

Jennings BM, Yoder LH, Heiner SL, Loan LA, Bingham MO. Soldiers with musculoskeletal injuries. J Nurs Scholarsh. 2008;40(3):268-74.

Goertz CM, Niemtzw R, Burns SM, Fritts MJ, Crawford CC, Jonas WB. Auricular acupuncture in the treatment of acute pain syndromes: A pilot study. Mil Med. 2006 Oct;171(10):1010-4.

**APPENDICES / SUPPORTING DATA:**

Study questionnaires/forms timeline attached.

**Auricular Therapy Trial: Therapy and Forms Timeline (Tx=Treatment)**

	Baseline	Post Tx 1	Weekly	Each Tx*	4 wk Post-Tx
<b>(Overall Forms)</b>					
<b>Consent</b>	X				
Demographics	X				
Pain / Medical History	X				
Current medications, treatments & efficacy	X				
<b>Brief Pain Inventory</b>	X	X	X		X
Pain: 1,2 & 24 hours post-tx		X			
<b>SF-8</b>	X		X		X
<b>Functional Ability Scale</b>	X	X	X		X
<b>Level of Relief</b>		X	X		X
<b>Change in Medication</b>			X		X
<b>(Breakdown by Form)</b>					
<b>Consent</b>	X				
<b>Post Treatment one Form</b>		X			
<b>Brief Pain Inventory</b>		X			
Pain: 1,2 & 24 hours post-tx		X			
<b>Functional Ability Scale</b>		X			
<b>Level of Relief</b>		X			
<b>SF-8</b>					
<b>Weekly Treatment Form</b>			X		
<b>Brief Pain Inventory</b>			X		
<b>Functional Ability Scale</b>			X		
<b>Level of Relief</b>			X		
<b>Change in Medication</b>			X		
<b>SF-8</b>			X		
<b>Post Treatment Form</b>					X
<b>Brief Pain Inventory</b>					X
<b>Functional Ability Scale</b>					X
<b>Level of Relief</b>					X
<b>Change in Medication</b>					X
<b>SF-8</b>					X
Tolerability/Satisfaction					X
<b>Clinician Intake Form</b>		X	X	X	X
Pre/Post tx pain level		X	X	X	X
Functional ability		X	X	X	X
Clinician Global Assessment		X	X	X	X
Auricular therapy form**		X	X	X	X

\*Use of Clinician Intake form will be based on the frequency of other treatments (i.e. physical therapy)

\*\*For subjects randomized to auricular therapy